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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 02/11/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	PAPER NUMBER
3763	15

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Advisory Action	Application No. 09/349,748	Applicant(s) BUCH-RASMUSSEN ET AL
	Examiner KCS 2/11/02 Kevin C. Simmons	Art Unit 3763

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 16 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-13 and 19-33*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s) _____.

10. ☐ Other: _____

Brian L. Casler
Primary Examiner

ntinuation of 2. NOTE: As to claims 1, 28, and 31, applicant has removed some limitations and has narrowed other limitations anging the scope of the claims, thus requiring a new search and consideration .

#16 Docket: 5533.200-US
3-8-02 RCE / 3763

Request for Continued Examination (RCE) Transmittal		
	Application Number	09/349,748
	Filing Date	July 8, 1999
	First Named Inventor	Thomas Buch-Rasmussen
	Group Art Unit	3763
	Examiner Name	Simmons, Kevin C.
	Attorney Docket Number	5533.200-US

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above identified application .

1. Submission required under 37 C.F.R. § 1.114:
   a. ☒ Previously submitted
      i. ☒ Consider the amendment under 37 CFR 1.116 previously filed on 1/16/02 (mailed 12/10/01).
      ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____.
      iii. ☐ Other: _____.
   b. ☐ Enclosed
      i. ☐ Amendment/Response
      ii. ☐ Affidavit(s)/Declaration(s)
      iii. ☐ Information Disclosure Statement
      iv. ☐ Other
2. Request for Extension of Time
   a. ☒ The applicant(s) respectfully request a 2 month further extension of time (3 months total extension)
3. Fees
   a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 19-2385.
      (i) ☒ RCE fee required under 37 C.F.R. § 1.17(e)
      (ii) ☒ Extension of time fee (37 C.F.R. §§1.136 and 1.17) ($920 less $110 previously paid = $810)
      (iii) ☒ Any other fees in connection with this communication.
   b. ☐ Check in the amount of $ _____ enclosed
   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Name	Robert B. Smith	Registration No.	28,538
Signature	Robert B. Smith	Date:	February 19, 2002

CERTIFICATE OF MAILING OR TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on:			
Name	Robert B. Smith		
Signature	Robert B. Smith	Date	February 19, 2002

03/05/2002 CNGUYEN 00000092 192385 09349748
01 FC:179 740.00 CH
02 FC:117 810.00 CH

Office Action Summary	Application No. 09/349,748	Applicant(s) BUCH-RASMUSSEN ET AL.	
	Examiner Kevin C. Simmons	Art Unit 3763	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19,21-23 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 19, 21-23 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01) Office Action Summary Part of Paper No. 17

DETAILED ACTION

Request for Continued Examination

The request filed on 2/19/02 for a Request for Continued Examination is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 19, 21-23 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device comprising: a cartridge assembly having a distal end and a proximal end (300), said distal end of the cartridge assembly comprising coupling means (303) for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge having one end with a pierceable seal (fig. 2 and 3) and having a stopper (125 or 355) adapted to receive a plunger means (figs. 1-4), a dosing assembly (figs. 1-4) comprising a plunger means for acting on said stopper and a mechanism for setting a specified dose and a driving means for advancing said plunger means to deliver the set dose (figs. 1-4), and a needle assembly including a coupling means for engaging the coupling means of said cartridge assembly to form a releasable coupling between said needle assembly and said cartridge assembly (figs. 1-4),

wherein the cartridge assembly and the dosing assembly are reliably coupled together, and wherein the combination of couplings between the dosing assembly and the cartridge assembly, and between the needle assembly and the cartridge assembly, respectively, is selected to ensure that the force applied to couple and decouple said needle assembly to and from said cartridge assembly does not cause said dosing assembly to move away from the cartridge assembly during coupling and decoupling of said needle assembly, such that said plunger means remains in abutment with said stopper during such coupling (figs. 1-4) and (The device of Chanoch is fully capable of performing the function of applicant's device.); 19, 21-23 and 25-27, (figs. 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed, however, it is not clear if Chanoch discloses a first and second releasable couplings that are of different types. Nevertheless, Chanoch clearly discloses other means for mounting the needle assembly to the cartridge assembly may be used (col. 8, lines 15-20). Therefore, it would have been obvious to one of ordinary skill at the time the invention was made to modify the releasable couplings of Chanoch to have various and different types of connections for quicker disconnection.

Response to Amendment

Drawings

Applicant's has amended the specification (page 5 of remarks). Therefore, the objections to the drawing have been removed.

Response to Arguments

Applicant's arguments with respect to claim1, 19, 21-23 and 25-33 have been considered but are not persuasive.

In response to applicant's statement that "The Examiner conceded that Chanoch does not disclose the concept of using two different couplings in the same device" applicant clearly has not read the rejection. The rejection without a doubt states that it is not clear if Chanoch discloses first and second releasable couplings that are of different types (see previous and above rejection).

Applicant's arguments are based on hypothetical hindsight. Applicant has not provided the examiner with any facts to support his arguments. It is request that applicant provide documented facts to support his arguments. It is the examiner position that one of ordinary skill in the art would not simply hold the dosing assembly when attempting to unscrew or screw the needle from the cartridge assembly. One would hold the cartridge assembly or the combination of the cartridge assembly and the dosing assembly when attempting to unscrew or screw the needle from the cartridge assembly.

Finally, Chanoch unmistakably discloses that different means for preventing and/or enabling rotation during the dose setting and injection phase may be provided. Similarly, other means for mounting needle cannula to the cartridge holder assembly may be provided (col. 8, lines 14-18). In simple terms, this means that there can be two different types of coupling means on a single device or the coupling means can be the same but something other than threads as shown in the figures.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons
Patent Examiner
5/14/02

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

3763

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Group Art Unit: 3763

Filed: July 8, 1999

Examiner: K. Simmons

Confirmation No: 7085

For: Medical Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment No Fee Transmittal
2. Amendment

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on August 15, 2002.

Tracy Bronner
(name of person mailing paper)

Tracy Bronner
(signature of person mailing paper)

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Group Art Unit: 3763

Filed: July 8, 1999

Examiner: K. Sirmons

Confirmation No: 7085

For: Medical Device

AMENDMENT NO FEE TRANSMITTAL

Commissioner for Patents
Washington, DC 20231

Sir:

Transmitted herewith is an Amendment for the above-identified application.

No fee extension fee is required for this Amendment as it is being submitted within the shortened statutory reply period. Please charge any and all additional fees that may due in connection with this paper or application, including the fee for the additional independent claim added by this amendment, estimated to be $84, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this authorization is attached.

Respectfully submitted,

Date: August 15, 2002

Marc A. Began Reg. No. 48,829
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748 Group Art Unit: 3763

Filed: February 11, 2002 Examiner: K. Sirmons

For: Medical Device

AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed May 15, 2002, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto, where applicable):

IN THE CLAIMS:

Please cancel claims 1-13 and 19-33 without prejudice or disclaimer.

Please add new claims 34-48 as shown below:

34. A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first and second coupling means are selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the first coupling means comprises a snap lock and wherein the snap lock is an integral part of the needle assembly.

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it

from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly; and

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly,

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly.

44. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first and second coupling means are chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling

means prevents axial movement of the cartridge assembly relative to the dosage assembly.

45. The medication delivery device of claim 44, wherein the dosage assembly comprises a plunger means and a drive means and wherein the second coupling means is selected to ensure that uncoupling of the needle assembly from the dosage assembly does not result in movement of the plunger means relative to a removable cartridge that is housed in the cartridge assembly.

46. The medication delivery device of claim 45, wherein the first coupling means comprises a snap-lock means for allowing axial coupling and uncoupling of the needle assembly to and from the cartridge assembly without the need to rotate the needle assembly relative to the dosage assembly.

47. The medication delivery decide of claim 46, wherein the second coupling means comprises a threaded coupling and wherein the first coupling means is at least partially integrated into the needle assembly.

48. The medication delivery device of claim 47, wherein the snap lock means is fully integrated into the needle assembly.

REMARKS

Claims 1-13 and 19-33 have been canceled without prejudice or disclaimer. Claims 34-48 have been added and therefore are pending in the present application. Claims 34-48 are supported by the drawings, the original claims, and the specification.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous office action, the Examiner rejected claims 1, 19, 21-23 and 25-27 under 35 USC § 102(b) in view of Chanoch US Pat. No. 5,688,251 and rejected claims 28-33 under 35 USC § 103(a) in view of Chanoch. The Examiner dismissed the Applicants' previous arguments that their invention is novel and non-obvious because Chanoch does not disclose selection of a means for securing the needle to cartridge assembly and a means for securing the dosing assembly to the cartridge assembly such that the dosing assembly does not move relative to the cartridge assembly during removal or attachment of a needle. The Examiner has, ostensibly, taken the position that one of ordinary skill in the art would grasp the Chanoch cartridge assembly or both the Chancoch cartridge assembly and the Chanoch dosing assembly when removing or attaching a needle and therefore the dosing assembly would not move relative to the cartridge assembly during a needle change. The Examiner, also asserts that because Chanoch states that other means for mounting the needle cannula to the cartridge holder may be provided, it discloses that two different types of coupling means on a single device or that something other than threads as shown in the figures may be used.

Applicants note that even if the Examiner's view of Chanoch is correct, Chanoch does not disclose or even suggest a means for ensuring that the dosing assembly does not move relative to the cartridge assembly when the dosing assembly and the needle are intentionally grasped during a needle change. Chanoch is silent as to how and what criteria should be used when selecting a means for securing the needle assembly to the cartridge assembly and the cartridge assembly to the dosing assembly. Moreover, Chanoch fails to disclose or even suggest that the two securing means should be chosen so that when force is applied to remove (or attach) the needle while the

dosage assembly is grasped, the security of the dosage assembly to the cartridge assembly is not jeopardized.

As presently claimed in the new pending claims (i.e., claims 34-48), Applicants' invention specifically requires that the means for securing the needle to the cartridge assembly and the means for securing the cartridge assembly to the dosing assembly be chosen so that when the needle assembly and the dosing assembly are grasped and a force applied to both to remove (or attach) the needle assembly, the cartridge assembly remains securely fixed to the dosing assembly. Thus, it is irrelevant to the patentability of the present claims whether one would grasp the cartridge assembly during a needle change. By their own terms, the claims now require that when the dosing assembly and needle assembly are grasped during needle attachment or removal, the means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly. By preventing the cartridge assembly from moving relative to the dosing assembly when changing a needle the accuracy of a subsequently administered dose can be guaranteed.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: August 15, 2002

Marc A. Began Reg. No. 48,829
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/349,748 Group Art Unit: 3763

Filed: Feb. 11, 2002 Examiner: K. Sirmons

For: Medical Device

AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the telephonic conversations between Examiner Sirmons and Marc A. Began (attorney for the Applicants) on Jan 16, 2003 and on Jan 21, 2003, please amend the above-captioned application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto, where applicable):

IN THE CLAIMS:

34. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein the snap lock is an integral part of the needle assembly..

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set dosage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper; and

wherein the first or second coupling means comprises a snap lock.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly;

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly; and

wherein at least the first or the second coupling means comprises a snap lock.

44. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the second coupling means is chosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

REMARKS

As per the Examiner's suggestion, the claims have been amended so that one of the coupling means comprises a snap lock. It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to

contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: January 21, 2003

Marc A. Began Reg. No. 48,829
Novo Nordisk
100 College Rd West
Princeton NJ 08540
(212) 867-0123

VERSION WITH MARKINGS TO SHOW CHANGES MADE

34. (Amended) A medication delivery device comprising:

a cartridge assembly comprising a cartridge having a pierceable seal at one end and a moveable stopper at an opposite end;

a dosage assembly comprising a plunger means for acting on the stopper; a mechanism for setting a specified dose; and a drive means for advancing the plunger means to deliver the specified dose;

a needle assembly;

a first coupling means for coupling and uncoupling the needle assembly to and from the cartridge assembly;

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the ~~first and~~ second coupling means ~~are~~is selected such that when a user grasps the needle assembly and applies a force to couple it to and to uncouple it from the cartridge assembly, while simultaneously grasping the dosage assembly and applying an equal but opposite force thereto, the cartridge assembly cannot not move axially with respect to the dosage assembly.

35. The medication delivery device of claim 34, wherein the first coupling means comprises a means for coupling or uncoupling the needle assembly through an axial movement of the needle assembly relative to the cartridge assembly and the second means comprises a threaded means.

36. The medication delivery device of claim 35, wherein the cartridge assembly comprises a housing for receiving the cartridge and wherein ~~the first coupling means comprises a snap lock and wherein~~ the snap lock is an integral part of the needle assembly.

37. A medication delivery device upon which a needle assembly can be mounted, the device comprising:

a cartridge assembly comprising a cartridge having a movable stopper at one end and a pierceable seal at an opposite end;

a dosage assembly comprising a mechanism for setting a specified dose, a plunger means for abutting the moveable stopper, and a drive means for driving the plunger means to deliver the set doseage;

a first coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly; and

a second coupling means for coupling and uncoupling a needle assembly to and from the cartridge assembly;

wherein the first and second coupling means are selected so that when a user grasps the needle assembly and applies force to the needle assembly to couple and uncouple it from the device while simultaneously grasping the dosage assembly and applying a equal and opposite force to the dosage assembly, the dosage assembly cannot move relative to the cartridge assembly, thereby ensuring that the plunger means remains abutted against the stopper and

wherein the first or second coupling means comprises a snap lock.

38. The medication delivery device recited in claim 37, wherein the second coupling means comprises a threaded coupling means and wherein the second coupling means comprises a means for coupling and uncoupling through an axial movement of the needle assembly relative to the cartridge assembly.

39. The medication delivery device of claim 37, wherein the first coupling means comprises a means for uncoupling through an axial movement of the cartridge assembly relative to the dosing assembly.

40. The medication delivery device of claim 37, wherein the first coupling means comprises a threaded coupling means.

41. The medication delivery device of claim 37, wherein the cartridge assembly comprises a housing to accommodate the cartridge and wherein the second coupling means comprises a means for axially coupling or uncoupling the needle assembly from the cartridge assembly.

42. The medication delivery device of claim 37, wherein the second coupling means comprises a threaded coupling means.

43. A medication delivery device comprising:

a cartridge assembly comprising:

a housing capable of housing a removable cartridge that has a pierceable seal at one end, is filled with medication, and has a moveable stopper at an opposite end that when moved toward the medication pressurizes the medication; and

a needle mounting means for mounting a needle on the cartridge assembly;

a dosage assembly for delivering a set dose of medication, comprising:

a plunger means for moving the stopper, a dose setting means for setting a dose, and a drive means for driving the plunger means to deliver the set dose, wherein after a portion of medication is expelled from the cartridge, the plunger means abuts the stopper;

a first means for coupling and uncoupling a needle assembly to and from the cartridge assembly; and

a second means for coupling and uncoupling the dosage assembly to and from the cartridge assembly,

wherein the first and second coupling means are chosen so that when a user simultaneously grasps the dosage assembly and the needle assembly and applies a force to the needle assembly to couple (or uncouple) the needle to or from the device the

cartridge assembly is positively precluded from moving axially relative to the cartridge assembly;

wherein at least the first or second coupling means comprises a snap lock.

44. A medication delivery device comprising:

a cartridge assembly for housing a removable cartridge containing a medication;

a needle assembly;

a dosage assembly comprising a mechanism for setting a dosage less than the full amount of medication contained in the cartridge;

a first coupling means for coupling and uncoupling the needle to and from a removable cartridge housed in the cartridge assembly; and

a second coupling means for coupling and uncoupling the cartridge assembly to and from the dosage assembly;

wherein the first coupling means comprises a snap lock; and

wherein the ~~first and~~ second coupling means are ischosen so that when a user couples or uncouples the needle assembly from the cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, the second coupling means prevents axial movement of the cartridge assembly relative to the dosage assembly.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,745	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

26137 7590 05/15/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Notice of Allowability	Application No. 09/349,748	Applicant(s) BUCH-RASMUSSEN ET AL.	
	Examiner Kevin C. Simmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/22/02.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☒ The drawings filed on 1/16/02 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
   * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

1. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

2. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. _____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

3. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Informal Patent Application (PTO-152)
3. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4. ☐ Interview Summary (PTO-413), Paper No. _____.
5. ☐ Information Disclosure Statements (PTO-1449), Paper No. _____.
6. ☐ Examiner's Amendment/Comment
7. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other .

DETAILED ACTION

Allowable Subject Matter

Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons
Patent Examiner
1/23/03

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26137 7590 01/27/2003

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	CLASS-SUBCLASS
3763	604-232000

DATE MAILED: 01/27/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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26137 7590 01/27/2003

PATENT DEPARTMENT
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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIMMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

1. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
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☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

26137 7590 01/27/2003

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

DATE MAILED: 01/27/2003

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 01/27/2003

26157 7590 01/27/2005

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

#21

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26137 7590 01/22/2003

~~PATENT DEPARTMENT~~ MARC A. BEGAN, ESQ.
~~SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP~~
~~FOUR TIMES SQUARE~~
~~NEW YORK, NY 10036~~
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540

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Raghida Haji	(Depositor's name)
R. Haji	(Signature)
4-28-03	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,748	07/08/1999	THOMAS BUCH-RASMUSSEN	5533.200-US	7085

TITLE OF INVENTION: MEDICAL DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	04/28/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIRMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Marc A. Began, Esq.
2 Richard W. Bork, Esq.
3 Reza Green, Esq.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☒ Issue Fee
☐ Publication Fee
☒ Advance Order - # of Copies 1

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 14-1447 (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) Reg No 48852-9 (Date) 4/28/03

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

05/06/2003 EAREGAY2 00000063 141447 09349748

01 FC:1501 1300.00 CH
02 FC:8001 3.00 CH

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

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Attorney Docket No.: 5553.200-US

PATENT

Certificate
AUG 10 2005
of Correction

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/349,748

Filed: July 8, 1999

For: Medical Device

Group Art Unit: 3763

Examiner: K. Simmons

Patent No.: 6,582,408

Issued: June 24, 2003

FACSIMILE CERTIFICATE OF TRANSMISSION
Via Facsimile No.: 571-273-8300

Certificates of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Request for Certificate of Correction of Patent for Applicant's Mistake (in duplicate)
2. Form PTO/SB/44 (also Form PTO-1050)

is being deposited with the United States Patent and Trademark Office via facsimile no. 571-273-8300 on August 9, 2005.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

AUG 12 2005

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Patent No. 6,582,408, issued Jun. 24, 2003
Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300
5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
Serial No.:	09/349,748
Examiner:	Kevin C. Sirmons

[redacted]

Certificates of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT
FOR APPLICANT'S MISTAKE [37 C.F.R. §1.323]

1. Patentees request correction of two errors in the above-referenced patent by issuance of a Certificate of Correction.

2. The first error appears in claim 1; col. 6, line 23. The text "cannot not move" (incorrect) should read "cannot move" (correct).

3. The second error appears in claim 10, col. 8, lines 5-7. The text "the cartridge assembly is positively precluded from moving axially relative to the cartridge assembly" (incorrect) should read "the cartridge assembly is positively precluded from moving axially relative to the dosage assembly" (correct).

4. Support for both of these corrections is found in the application as originally filed at page 4, lines 21-26; and in the issued patent at col. 3, lines 15-22:

> "In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle

AUG 1 2 2005

assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly."

The correct information also appears in the prosecution history in the Amendment dated August 15, 2002, at page 7, first full paragraph: "[T]he means for securing the dosing assembly to the cartridge assembly must prevent unintended axial movement of the dosage assembly relative to the cartridge assembly."

5. In each instance, the mistake is of a clerical nature, of minor character and self-evident. In view of the support in the application as filed, as well as the clear purport of the claim language, the requested corrections would not involve new matter, nor would they require reexamination of the application.

6. Attached is a copy of Form PTO/SB/44 (also Form PTO-1050), specifying a correction to each of the errors.

7. Please authorize and issue the Certificate of Correction to the undersigned Attorney.

Patentees attach copies of the relevant pages from the prosecution history.

8. The Commissioner is authorized to charge the fee for this Petition for Certificate of Correction per 37 C.F.R. §1.20(a), and any additional fees which may be due, to Deposit Account No.14-1447.

Dated: August 9, 2005

Respectfully submitted,

Marc A. Began
Reg. No. 48,829
Customer No. 23650
Novo Nordisk
100 College Road West
Princeton, NJ 08540
Direct Line: (609) 919-7829

Enclosures

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Patent No. 6,582,408, issued Jun. 24, 2003
Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300

5533.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
Serial No.:	09/349,748
Examiner:	Kevin C. Simmons

Certificates of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Attorney Docket No.: 5533.200-US
Via Facsimile No.: 571-273-8300

5533.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:	6,582,408
Issued:	June 24, 2003
Name of Patentee:	Buch-Rasmussen et al.
Title of Invention:	Medical Device
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Examiner:	Kevin C. Sirmons

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Patent No: 6,582,408 B1
Issued: June 24, 2003
Name of Patentee: Buch-Rasmussen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 6
Line 23: "cannot not move" should read "cannot move".

Col. 8
Line 7: "cartridge assembly" should read "dosage assembly".

MAILING ADDRESS OF SENDER:
Marc A. Began, Esq.
Novo Nordisk, Inc.
100 College Road, West
Princeton, NJ 08540

AUG 12 2005

08/09/2005 14:25 FAX 6099373095 NOVO NORDISK FINANCL RECEIVED 008/008
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AUG 0 9 2005

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

Patent No: 6,582,408 B1
Issued: June 24, 2003
Name of Patentee: Buch-Rasmussen et al.

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Line 23: "cannot not move" should read "cannot move". A

Col. 8
Line 7: "cartridge assembly" should read "dosage assembly". A

MAILING ADDRESS OF SENDER:
Marc A. Began, Esq.
Novo Nordisk, Inc.
100 College Road, West
Princeton, NJ 08540

PAGE 8/8 * RCVD AT 8/9/2005 3:16:16 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/31 * DNIS:2738300 * CSID:6099873095 * DURATION (mm-ss):01-38
AUG 1 2 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,582,408 B1
DATED : June 24, 2003
INVENTOR(S) : Buch-Rasmussen et al.

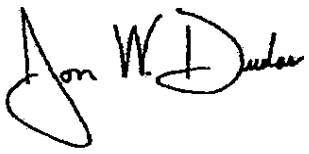
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,
Line 23, "cannot not move" should read -- cannot move --.

Column 8,
Line 7, "cartridge assembly" should read -- dosage assembly --.

Signed and Sealed this

Thirteenth Day of September, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

Attachment for PTO-948 (Rev. 03/01. or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application.

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6/18/01

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ATTACHMENT TO AND MODIFICATION OF NOTICE OF ALLOWABILITY (PTO-37)

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored:

~~A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to~~ ~~EXPIRE THREE MONTHS FROM THE DATE MAILED of this Office action. Failure to comply will result in~~ ~~ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

---

[1] The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See *Changes to Implement the Patent Business Goals*, 65 *Fed. Reg.* 54603, 54629, 54631, 54670, 54674 (September 8, 2000), 1238 *Off. Gaz. Pat. Office* 77, 99, 110, 135, 139 (September 19, 2000).

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6/18/01

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All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes

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Failure to take corrective action within the set period will result in ABANDONMENT of the application.

06/01 01

PATENT APPLICATION FEE DETERMINATION RECORD

Effective November 10, 1998

Application or Docket Number: 09/849,748

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	18 minus 20=	* —
INDEPENDENT CLAIMS	2 minus 3 =	* —
MULTIPLE DEPENDENT CLAIM PRESENT		

SMALL ENTITY TYPE ☐	RATE	FEE	OR	OTHER THAN SMALL ENTITY	RATE	FEE
		380.00	OR			760.00
X$ 9=			OR	X$18=		
X39=			OR	X78=		
+130=			OR	+260=		
TOTAL			OR	TOTAL		760

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

A

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 33	Minus	** 20	= 13
Independent	* 4	Minus	*** 3	= 1
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	26	520.00
X39=			OR	X78=	87.00	
+130=			OR	+260=		
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE		

D

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 11	Minus	** 20	= —
Independent	* 4	Minus	*** 4	= —
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

No fee needed

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=		
X39=			OR	X78=		
+130=			OR	+260=		
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE		

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY	RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY	RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=		
X39=			OR	X78=		
+130=			OR	+260=		
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE		

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 6/98)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
604	186/187 232/188 192/195 207-218 200,201 228,233 234	11/16/00	KCS
Update	search	5/14/02	KCS
Update	search	1/23/03	KCS

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
East	11/14/00	KCS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Same	as above	1/23/03	KCS

(RIGHT OUTSIDE)

ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	S.W.	399 6209	1-26-99
O.I.P.E. CLASSIFIER	MDM	59	1-26-99
FORMALITY REVIEW		66703	8-3-99

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral)... Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date
1	1	2/26
2	2	11/26
3	3	9/23/04
4	4	5/18/05
5	5	11/23/05
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Claim Final	Claim Original	Date
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If more than 150 claims or 10 actions staple additional sheet here

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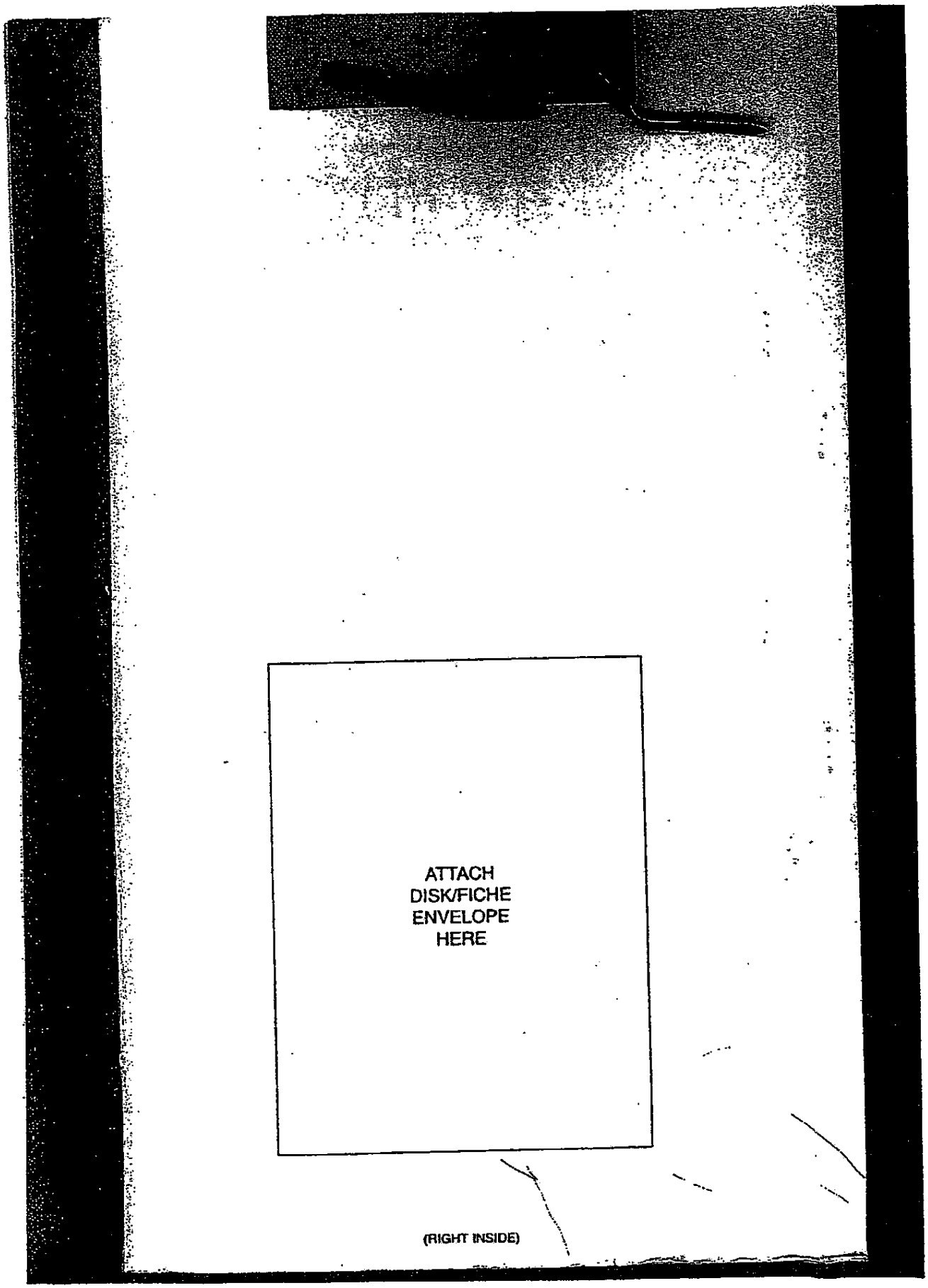
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PATENT APPLICATION
09349748

INITIALS

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